

SN 10/629,984
Docket No. S-100,648
In Response to Office Action dated 04.21.05

REMARKS

1. Status Information:

Claims 1-16 are pending. Claims 11-16 have been withdrawn pursuant to applicants response/election in reply to a restriction requirement. Additionally, the examiner has withdrawn claims 5, 6, and 9, as being drawn to a non-elected species. Claims 1, 2, 3, 4, 7, 8 and 10 have been examined.

2. Amendments to the Specification:

The specification has been amended to recite incorporation by reference language applicable to all publications, patents and patent applications cited in the specification. This amendment does not introduce new matter.

3. Amendments to the Claims:

Claim 1 has been amended to limit the claim to a "trifunctional chemical moiety", to set out that the anchoring groups are "hydrophobic membrane anchoring groups" that allow attachment to membrane surfaces such as a lipid membrane surface as described in the specification, and to set out that the anchoring groups are "one functionality" of the trifunctional chemical moiety. Claim 2 has been cancelled in view of the amendment to claim 1. Claim 3 has been amended to limit the claim to a "trifunctional chemical moiety" and the dependency of claim 4 has been changed.

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4. Lack of Written Description Rejection (35 USC 112, 1st paragraph):

Claims 1-4, 7, 8 and 10 were rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner argues that the presence of a single working example is insufficient, in view of a claimed genus encompassing virtually an infinite number of compounds and/or compositions. The examiner argues that solid phase synthesis was not sufficiently routine or predictable at the time the application was filed, concluding that one of skill in the art would not be able to devise strategies for the use of any solid support containing a multifunctional moiety having any active sites protected in any way.

Claims 1, 3, 4, 7, 8 and 10, as herein amended, are drawn to compositions comprising a solid resin support having a trifunctional chemical moiety covalently attached thereto at a resin attachment site, the trifunctional chemical moiety including a hydrophobic membrane anchor as one of the functionalities.

The claims must be viewed and interpreted in light of the specification. The specification contains limitations that relate to the scope of the amended claims. For example, the nature of the trifunctional chemical moiety is clearly set out in the specification (see, e.g., specification at page 3, line 17 through page 4, line 5; see also, FIG. 1). Limitations relating to the membrane anchor recited in amended claim 1 include the limitation of alkyl, alkenyl, alkynyl, and polyaromatic hydrophobic chains of carbon containing from about 4 to 30 carbons. The incorporation of these hydrophobic chains is well known.

The term "derivative" when used in claims 3 and 4 to modify "amino acid" is well known to those skilled in the art, and does not introduce any indefiniteness into

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the claim. In addition, to those skilled in the art of solid phase synthesis, the chemistries associated with modifying amino acids are well known.

Although the claims are drawn to numerous structural variants, the chemistries associated with creating embodiments of the compositions claimed are well known, routine, and well within the scope of the ordinarily skilled artisan. Moreover, applicants suggest that the requirement for "representative examples" must be taken in view of the state of the art. In cases where the techniques required to practice the invention are well known, there is no need for multiple examples to communicate to those skilled in the art that the applicant is in possession of the full scope of the invention. The specification need not contain any example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Here, the solid phase chemistries required to create the claimed compositions were very well known at the time the invention was made. In the practice of the invention, standard techniques are used to build the reactive group, the reactive arm group and the membrane anchor functionalities. The key common component of the claimed compositions is the trifunctional chemical moiety, as specifically defined in the specification. Modifications of the reactive groups/functionalities, of any kind, are well within the abilities of those skilled in the art. Therefore, the invention is disclosed in a manner that enables one skilled in the art to make the claimed compositions without undue experimentation, and applicants should not be burdened with a requirement for multiple examples reproducing multiple standard synthesis routines.

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5. Lack of Enablement Rejection (35 USC 112, 1st paragraph):

Claims 1-4, 7, 8 and 10 were also rejected under 35 USC 112, first paragraph, as failing to reasonably provide enablement for any multifunctional group bound to any resin containing any anchoring group.

Claims 1, 3, 4, 7, 8 and 10, as herein amended, are drawn to compositions comprising a solid resin support having a trifunctional chemical moiety covalently attached thereto at a resin attachment site, the trifunctional chemical moiety including a membrane anchor. Examples of such trifunctional chemical moieties are known as shown in U.S. Patent No. 6,627,396 for an influenza sensor. The membrane anchor is well defined in the specification (see above), and the chemistries needed to modify amino acids with hydrophobic chains are well known. Indeed, modified amino acids, containing variable length hydrophobic chains, are commercially available. As discussed above, the chemistries needed to synthesize reactive groups (the other two functionalities of the trifunctional chemical moiety) are well known and well within the ordinary level of skill in the art.

Accordingly, although the claims are drawn to numerous structural variants, the chemistries associated with creating embodiments of the compositions claimed are well known, routine, and well within the scope of the ordinarily skilled artisan. The examiner contends that there are an infinite number of possibilities included in the claims. Applicants have amended the claims to more precisely define the invention, and contend that the breadth of the claims is reasonable. The examiner also contends that solid phase synthesis was not sufficiently routine and that the nature of the invention is unpredictable. Applicants respectfully disagree, as solid phase chemistry has been known for decades, has been used in automated synthesis instruments since the early 1980s, and is in widespread use worldwide. The chemistries needed for modifying the reactive groups of the claimed compositions are well known and predictable. The resins suitable for use

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in the practice of the invention are also well known, and the specification states that solid resin supports useful in the practice of the invention are those which are *conventionally* used for solid phase synthesis (see, page 11, line 1). Protecting chemistries are also well known, and are also specifically described in the specification (see, page 9, lines 4-25).

As above, applicants suggest that the requirement for "representative examples" must be taken in view of the state of the art. The specification need not contain any example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Here, the solid phase chemistries required to create the claimed compositions were very well known at the time the invention was made. In the practice of the invention, standard techniques are used to build the reactive group, the reactive arm group and the membrane anchor functionalities. The key common component of the claimed compositions is the trifunctional chemical moiety, as specifically defined in the specification. Modifications of the reactive groups/functionalities, of any kind, are well within the abilities of those skilled in the art. In the subject application, the specification does contain a working example. Together with the knowledge in the art and predictability of solid phase synthetic chemistries, the invention is disclosed in a manner that enables one skilled in the art to make the claimed compositions without undue experimentation.

Applicants respectfully request reconsideration and withdrawal of the rejection in view of the amendments made to the claims and the foregoing remarks.

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6. Indefiniteness Rejection (under 35 USC 112, 2nd paragraph):

Claims 1-4, 7, 8 and 10 were rejected under 35 USC 112, second paragraph, as being indefinite, as follows:

For claim 1, and all claims dependent thereon, the phrase "said multifunctional chemical moiety including hydrophobic anchoring groups" is deemed vague and indefinite, since it is unclear whether the hydrophobic anchoring groups are part of the multifunctional group or are a separate entity apart from the multifunctional group. In addition, the examiner indicates that the claim does not provide a point of reference with regard to the "anchoring" function, questioning whether the hydrophobic groups are anchoring to the solid support or some other chemical moiety.

The claims have been amended to more particularly claim the subject invention. Specifically, claim 1 has been amended to limit the claim to a "trifunctional chemical moiety", to set out that the anchoring groups are "hydrophobic membrane anchoring groups" that allow attachment to membrane surfaces such as a lipid membrane surface as described in the specification, and to set out that the anchoring groups are "one functionality" of the trifunctional chemical moiety.

In response to the examiner's question concerning the carboxylic acid group as the reactive arm group, applicants note that the trifunctional chemical moiety may contain two carboxylic acid reactive groups.

Accordingly, applicants have rectified the indefiniteness issues raised by the examiner, and therefore request reconsideration and withdrawal of this rejection.

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7. Rejection under 35 USC 102(b) – Anticipation by Singh et al.

Claims 1-4, 7, 8 and 10 were rejected under 35 USC 102(b) as being anticipated by Singh et al., 2000, Tetrahedron Letters 41: 9601-05 ("Singh").

None of the compounds disclosed in Singh anticipate a composition comprising a solid resin to which a trifunctional chemical moiety of the invention is covalently attached, as none of the Singh compounds contain the membrane anchor limitation as taught by the subject application. The trifunctional chemical moiety of the invention, as defined in the specification, comprises a "membrane anchor" (see, e.g., the specification at page 3, line 19). The "membrane anchor" provides mobile attachment of the trifunctional chemical moiety to a fluid surface of a membrane (see, e.g., the specification at page 4, lines 1-3). The importance of the membrane anchor for the presentation of ligands on membranes and cell surfaces is clearly stated in the application. Singh do not in any manner address the application of a multifunctional chemical moiety to membranes and cell surfaces. Membrane anchor functionality is simply not disclosed or suggested by Singh.

The use of a membrane anchoring sidechain on an amino acid immobilized on a solid support is novel and unrelated to what is reported in Singh. The hydrophobic groups disclosed in Singh and cited by the examiner in the rejection are introduced post-synthetically, after solid phase synthesis, and are not part of the "on resin" assembly taught by the subject application.

Accordingly, Singh does not anticipate the invention claimed in amended claims 1, 3, 4, 7, 8 and 10. Applicants respectfully request reconsideration and withdrawal of the rejection in view of the amendments made to the claims and the foregoing remarks.

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8. Rejection under 35 USC 102(b) – Anticipation by Meienhofer et al.

Claims 1-4, 7, 8 and 10 were rejected under 35 USC 102(b) as being anticipated by Meienhofer et al., 1971, PNAS 68: 1006-09 ("Meienhofer").

None of the compounds disclosed in Meienhofer anticipate a composition comprising a solid resin to which a trifunctional chemical moiety of the invention is covalently attached, as none of the Meienhofer compounds contain the membrane anchor limitation as taught by the subject application. The trifunctional chemical moiety of the invention, as defined in the specification, comprises a "membrane anchor" (see, e.g., the specification at page 3, line 19). The "membrane anchor" provides mobile attachment of the trifunctional chemical moiety to a fluid surface of a membrane (see, e.g., the specification at page 4, lines 1-3).

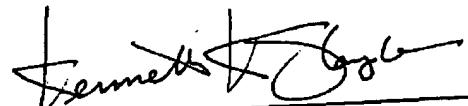
The importance of the membrane anchor for the presentation of ligands on membranes and cell surfaces is clearly stated in the application. Meienhofer do not in any manner address the application of a multifunctional chemical moiety to membranes and cell surfaces. Membrane anchor functionality is simply not disclosed or suggested by Meienhofer. The use of a membrane anchoring sidechain on an amino acid immobilized on a solid support is novel and unrelated to what is reported in Meienhofer. The hydrophobic groups disclosed in Meienhofer and cited by the examiner in the rejection are introduced post-synthetically, after solid phase synthesis, and are not part of the "on resin" assembly.

Accordingly, Meienhofer does not anticipate the invention claimed in amended claims 1-4, 7, 8 and 10. Applicants respectfully request reconsideration and withdrawal of the rejection in view of the amendments made to the claims and the foregoing remarks.

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In view of the foregoing amendments and remarks presented in reply to the Office Action, applicants respectfully request reconsideration and withdrawal of all pending rejections against claims 1-4, 7, 8 and 10. These claims now being in condition for allowance, applicants respectfully request an early indication of the same.

Respectfully submitted,



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